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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/630,402

07/30/2003

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11/20/2008

EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

11/20/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |  |  |
|------------------------------|--|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/630,402   | <b>Applicant(s)</b><br>FLAHERTY, PATRICE |  |
|                              | <b>Examiner</b><br>JEFFREY G. HOEKSTRA | <b>Art Unit</b><br>3736                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-32 is/are pending in the application.
- 4a) Of the above claim(s) 12-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-11 and 24-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/06/2008 has been entered.

### ***Notice of Amendment***

2. In response to the amendments filed on 10/06/2008, amended claim(s) 1, 7, 24, and 30-32 and cancelled claim(s) 8 is/are acknowledged. The current rejections of the claim(s) 1-7, 9-11, and 24-32 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-7, 9-11, and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Propp (US 5,919,146) in view of Prager (US 4,257,416).

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5. For claims 1, 2, 4, 5, 7, 10, 24, and 26, Propp discloses a multi-channel bodily-fluid handling device (as best seen in Figure 1), wherein said fluid is capable of being blood, comprising:

- a main tubing segment (40) for the passage of bodily fluids;
- an indicator unit (48 and 20) and an access port (30) disposed in fluid communication with said main tubing segment and in a branched relationship to each other, wherein both the indicator unit and access port are associated with respective connective tubing conduits or legs (44 and 32, respectively), wherein said indicator unit comprises a fluid volumeter chamber (48 or 56) adapted for indicating fluid volume (column 2 lines 7-11 and column 3 lines 36-58), wherein said indicator unit has a first end (the bottom end of 20 as best seen in Figure 1) disposed in fluid communication with said main tubing segment and a second end (the upper end of 48 as best seen in Figure 1), and wherein an air flow pathway inherently extends through said fluid volumeter between said first and second ends and coincides with a liquid flow pathway (as best seen in Figure 1);
- a clamp (74) operably engaging said main tubing segment for selectively blocking fluid; and
- an air-permeable liquid-impervious membrane (60) disposed in fluid communication with said fluid volumeter at said second end of said fluid volumeter (as best seen in Figure 1) (column 3 lines 36-41 and column 4 lines 11-21),
- wherein said fluid volumeter is disposed between said main tubing segment and said at least one air-permeable liquid-impervious membrane (as best seen in Figure 1)

and allows bidirectional fluid movement between and through said fluid volumeter and said access port (as best seen in Figure 1).

6. For claims 3, 6, 9, and 11, Propp discloses a multi-channel bodily-fluid handling device wherein said indicator unit is disposed in removable fluid communication with said main tubing segment via a second clamp (64) or via disassembly.

7. For claims 25 and 31, Propp discloses a multi-channel bodily-fluid handling device, further comprising: a connector (46) disposed in fluid communication with said main tubing segment, disposed in removable fluid communication with said indicator unit via a third clamp (54) or via disassembly, and between said clamp and said indicator unit and said port (as best seen in Figure 1).

8. For claim 27, Propp discloses a multi-channel bodily-fluid handling device, further comprising: a collector conduit (56, or 68) disposed in fluid communication with said main tubing segment via said indicator unit tubing conduit and disposed in fluid communication with said indicator unit.

9. For claim 28, Propp discloses a multi-channel bodily-fluid handling device wherein said indicator unit comprises a volumeter conduit (66) disposed in fluid communication with said collection conduit and disposed in fluid communication with said volumeter conduit.

10. For claim 29, Propp discloses a multi-channel bodily-fluid handling device, further comprising: a port (62) disposed between said collector and volumeter conduits.

11. For claims 30 and 32, Propp discloses a multi-channel bodily-fluid handling device, further comprising: said access port tubing conduit or leg disposed in fluid

communication with said main tubing segment and in a branched relationship to a collector tubing leg, and wherein said access port is disposed on said access tubing segment.

12. Thus for claims 1-7, 9-11, and 24-32, Propp discloses the multi-channel bodily-fluid handling device, as set forth and cited above, except for expressly disclosing (a) the fluid comprises blood; (b) the fluid volumeter and the access port are disposed in bidirectional fluid communication with the main tubing segment; and (c) the clamp operably engaging the main tubing segment and adapted to selectively block and unblock fluid flow in both directions therethrough. Prager teaches multi-channel blood aspiration and fluid infusion device (as best seen in Figure 1) configured for introducing fluids into a patient and permitting withdrawal of blood samples (Abstract), comprising *inter alia*: (a) the fluid comprises blood (Abstract); (b) a fluid volumeter (45) (column 3 line 60 – column 4 line 21) and an access port (34 or 38) (column 3 line 60 – column 4 line 21) are disposed in bidirectional fluid communication with a main tubing segment (16) (Abstract) (as best seen in Figure 1) (column 5 lines 39-45); and (c) a clamp (52) operably engaging the main tubing segment (as best seen in Figure 1) and adapted to selectively block and unblock fluid flow in both directions therethrough (Abstract, column 2 lines 12-19). The claimed invention would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Propp and Prager teach elements of bodily-fluid handling devices, it would have been obvious to one skilled in the art at the time of the invention to substitute one element of a bodily-

fluid handling device for the other to achieve the predictable results of providing an alternate configuration of a bodily fluid handling device to decrease patient discomfort by using a bodily fluid handling device permitting both aspiration and infusion.

### ***Response to Arguments***

13. Applicant's arguments with respect to claims 1-7, 9-11, and 24-32 have been considered but are moot in view of the new ground(s) of rejection, wherein the new ground(s) of rejection relies upon a new and/or different interpretation of previously applied prior art and/or includes a new and/or different obviousness-type motivational statement.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra  
Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736